



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/609,053

06/27/2003

Richard A. Gambale

B0410/7275D1

6907

22832 7590 11/14/2008  
K&L Gates LLP  
STATE STREET FINANCIAL CENTER  
One Lincoln Street  
BOSTON, MA 02111-2950

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

11/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/609,053	<b>Applicant(s)</b> GAMBALE ET AL.	
	<b>Examiner</b> CHRISTOPHER D. KOHARSKI	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 12-16, 19 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-16, 19 and 25-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/11/2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the reply filed 7/11/2008 in which claims 12 and 25-27 were amended and new claim 28 was added. Currently claims 12-16, 19, and 25-28 are pending for examination in this application.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) that was submitted on 7/11/2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 12, Applicant's Representative asserts that the resilient members are directly attached to the shaft. The Examiner does not see the member being directly attached to the shaft; each member is attached via the attachment bands (30, 26) in Applicant's instant invention (Figure 1). For the purposes of examination the Examiner will assume that the members are fixed to the shaft via additional elements constitutes direct fixation.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-15 and 25-28 are rejected under 35 U.S.C 103(a) as being unpatentable over Khosravi (USPN5,415,637) in view of Hammerslag et al. (USPN5,372,587). Khosravi discloses a temporary stenting catheter with drug delivery capabilities.

Regarding claims 12-15 and 25-28, Khosravi discloses a catheter-based procedure to a particular treatment site within a patient comprising: providing a catheter (Figures 1-1a) comprising a tubular shaft (10) having a proximal end and a distal end and a radially extendible tissue engagement mechanism (28) at its distal end, the radially extendible tissue engagement mechanism comprising a plurality of resilient members (28) configured to be selectively engaged so that the resilient members extend radially outward from a longitudinal axis (along 7), each having proximal and

Art Unit: 3763

distal ends, all distal ends joined together (31) and fixed longitudinally relative to the shaft adjacent its distal end and all proximal ends joined together (near 28e) and to the shaft at a position proximal to the distal end such that the resilient members lie parallel and are actuated by a pull wire (13); navigating the catheter so that the distal end is adjacent to the intended treatment site (for drug delivery); causing the tissue engagement mechanism to extend into engagement with the tissue col 5, ln 10-40) adjacent to the treatment site; and performing the procedure while maintaining the tissue engagement mechanism in its extended position (Figures 1-1a, cols 1-2).

Khosravi meets the claim limitations as described above except for the express limitation of the distal shaft end rotating through an angular displacement.

However, Hammerslag et al. teaches a steerable medical device.

Regarding claims 12-15 and 25-27, Hammerslag et al. teaches a catheter (210, Figures 24-26) with a pull wire (234) that causes the distal end of the shaft to rotate through an angular displacement when a compressive load is applied to pull wire (234) (Figures 24 and 25, cols 1-2).

At the time of the invention, it would have been obvious to operate the catheter of khosravi in the manner described of Hammerslag et al. to allow for distal end steering; both catheters have offset pull wires which would provide distal end motion during actuation of the pull wire. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hammerslag et al. (cols 1-2).

***Claim Rejections - 35 USC § 103***

Claims 16 and 19 are rejected under 35 U.S.C 103(a) as being unpatentable over Khosravi (USPN5,415,637) in view of Hammerslag et al. (USPN5,372,587) in further view of Edwards et al. (USPN5,461,982). The modified Khosravi meets the claim limitations as described above except for the electrical detection and thermal intervention.

However, Edwards et al. teaches a cardiac mapping and ablation system.

Regarding claims 16 and 19, Edwards et al. teaches a catheter (10) with a distal end (20) with cardiac sensing and thermal electrodes (20) (col 4, ln 25-50).

At the time of the invention, it would have been obvious to add the electrical electrode components of Edwards et al. to the modified system of Khosravi in order to add additional diagnostic functions. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Edwards et al. (cols 1-2).

***Response to Arguments***

Applicant's arguments filed 07/11/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that the combination of Khosravi (USPN5,415,637) in view of Hammerslag et al. (USPN5,372,587) does disclose all distal ends of the resilient members being joined together and fixed longitudinally directly to the shaft adjacent the distal end of the shaft and that the resilient members lie parallel to the longitudinal axis along and adjacent the shaft when unloaded.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the prior art of record meets the claimed limitations. Khosravi does disclose all distal ends of the resilient members (28) being joined together (via 31) and fixed longitudinally directly to the shaft (10) adjacent the distal end (near 28e, via the member 31 and shaft extension 29) of the shaft (10) and that the resilient members (28) lie parallel to the longitudinal axis (the series of planes that extend from 41 through 33) along and adjacent the shaft when unloaded (see Figures 1a, wherein the members are expanded and still adjacent the distal end). Examiner further asserts that the distal end of the shaft can terminate near element 28e or be extended further via members 29 and 31, additional several longitudinal axes and planes are present for the resilient members to lie parallel with. Examiner suggests further clarification of the longitudinal planes and the shaft distal end/attachment (see below).

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

#### ***Suggested Subject Matter***

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification of the flexible member and catheter fixation points (30, 26) as shown in Applicant's Figure 1 and in the prior amendments with respect to the planes of the shaft and the resilient members overlaying the shaft before the compressive load and the resilient members being attached to the distal shaft end.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 10/23/2008

/Christopher D Koharski/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763